DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 24, 2015

Cook, Inc.
% Mr. Steven Lawrie
Regulatory Affairs Team Lead
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K142819
Trade/Device Name: Shuttle-SL Flexor Tuohy-Borst Side-Arm Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 16, 2015
Received: June 17, 2015

Dear Mr. Lawrie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142819

Device Name
Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set

Indications for Use *(Describe)*
Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) Summary

Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Steven Lawrie
Email:	steven.lawrie@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 104518
Contact Fax Number:	812-332-0281
Date Prepared:	June 16, 2015

Device Information:

Trade Name:	Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set
Common Name:	Introducer Set
Classification Name:	Introducer, Catheter DYB (21 CFR §870.1340)

Predicate Devices:

The Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set is substantially equivalent to the following devices: the Pinnacle® Destination® Peripheral Guiding Sheath (K091329) cleared on May 29, 2009 and the Cordis Brite Tip® Catheter Sheath Introducer (K984500) cleared on December 23, 1998.

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Device Description:

The Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set is composed of an introducer sheath and a dilator. These devices will be manufactured in 4.0, 5.0, 6.0, 7.0, and 8.0 French and in lengths of 80, 90 and 110 centimeters.

The Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Sets are manufactured with a polycarbonate Tuohy-Borst proximal fitting on a Teflon lined, coil-reinforced nylon introducer sheath (Flexor® material). The dilator (composed of nylon or polyethylene depending on French size) is characterized by a distal taper allowing for a smooth transition with the appropriately sized wire guide. A hydrophilic coating is applied to the distal portion of both the sheath and dilator components

The Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer Set is designed specifically to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature. Using the Seldinger technique, the physician gains percutaneous access to the vascular system and then employs the Shuttle-SL introducer sheath as a conduit for inserting diagnostic and/or interventional devices into the patient.

Comparison to Predicates:

The proposed device is substantially equivalent to the predicates in terms of intended use, duration of use, principles of operation, technological characteristics, and insertion method. The proposed device has the same components (introducer sheath and dilator) with the same or comparable materials as those of the predicate devices. Additionally, the specifications of the proposed device components generally fall within the range of those of the predicate devices. The differences between the subject device and the two predicate devices, including intended use language, material (e.g., proximal fitting, coating, dilator), dilator wire guide compatibility, and shelf-life, do not raise any new issues of safety and effectiveness.

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Intended Use:

Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Test Data:

The proposed Shuttle®-SL Flexor® Tuohy-Borst Side-Arm Introducer was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time) demonstrated that the device is biocompatible. In conformance with the applicable sections of AAMI/ANSI/ISO 10993-1:2009, the predetermined acceptance criteria were met.
- Dilator and introducer sheath tensile testing – Testing verified that under proper clinical use of the dilator and introducer sheath, the peak load values shall be in accordance with the applicable values of BS EN ISO 11070:1999. The predetermined acceptance criteria were met.
- Dilator and introducer sheath liquid leakage – Testing verified that under proper clinical use of the dilator and introducer sheath, each test article shall not leak when tested in accordance with BS EN ISO 11070:1999, Annex D and E. The predetermined acceptance criteria were met.
- Dilator and introducer sheath mechanical abrasion – Testing verified that the hydrophilic coating for the device met the requirements for durability. The predetermined acceptance criterion was met.
- Dilator and introducer sheath lubricity – Testing verified that, while hydrated and subjected to a 300 gram normal force, the peak force over a 10 centimeter stroke shall be less than 100 gram during the course of 10 cycles. The predetermined acceptance criteria were met.
- Thromboresistance testing – Testing verified that there would be 0% to 25% estimated patency impact due to thrombus associated with the test articles. The predetermined acceptance criterion was met.

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- Acute performance – Testing verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.
- Coating integrity and device compatibility testing under simulated use – Testing verified that the coating appearance was absent of defects before and after simulated use.
- Dimensional verification testing – Testing verified that the dilator can accept the appropriately sized wire guide, the dilator can pass through the sheath, the inner diameter of the sheath is within the specified French size, and the sheath length is within a specified tolerance.
- Torque strength testing – Testing verified that under proper clinical use, the device could withstand one full rotation without failure.

In conclusion, the results of these tests support a determination of substantial equivalence.